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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/002,536 | 11/01/2001 | Michael D. Kane | 65446-0087 | 3282 |

10291 7590 07/20/2004

RADER, FISHMAN & GRAUER PLLC
39533 WOODWARD AVENUE
SUITE 140
BLOOMFIELD HILLS, MI 48304-0610

EXAMINER

WILDER, CYNTHIA B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1637

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,536

Applicant(s)

KANE ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/20/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's preliminary amendment filed on July 23, 2002 is acknowledged and has been entered.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-32 in the reply filed on April 27, 2004 is acknowledged.

Oath/Declaration

3. It is acknowledged that this application is accorded Rule 1.47(a) status. Accordingly, the Oath/Declaration is acceptable.

Specification

4. The disclosure is objected to because of the following informalities: The specification is objected to at paragraphs 0009, 0019, 0020, 0026, 0034, and 0051 because the designation for the sequence identifier (SEQ. ID NO.) is improper. It is suggested changing "SEQ. ID NO." to "SEQ ID NO:" (see MPEP 2422.03).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohroki et al (Biochemical and Biophysical Research Communications, vol. 262, pages 365-367, August 1996) in view of Loewy. (US 5, 914229, June 1999). Regarding claims 1-2 5-6, 9-10, 13-14, 17-18, 21-22, 25-26 and 29-30, Kohroki et al teach a method for the identification and characterization of gene expression in one or more samples, comprising: one or more RNA molecules, providing an indentimer comprising an oligo-dT primer sequence from 5' 3' end wherein said indentimer also comprises a detectable marker at one end; contacting the RNA with the indentimer such that the poly T portion of the indentimer hybridizes to a polyA tail of the RNA; reverse transcribing the mRNA to produce a first strand cDNA that includes the indentimer, synthesizing a second DNA strand complementary to the first strand cDNA to form a duplex; cleaving the duplex with at least one sequence-specific cleaving agent to provide one or more duplex cleavage fragments, ligating an adaptamer to one or more of said cleavage fragments and amplifying the one or more ligated cleavage fragments using the indentimer to produce one or more amplified fragments comprising sequences complementary to a 3' end of the mRNA (see entire reference, especially Figure 1).

Kohroki et al differs from the instant invention in that the reference does not expressly teach wherein the adaptamer comprises an RNA polymerase promoter site or wherein the amplifying one or more ligated cleavage fragments occur by means of *in vitro* transcription using one or more RNA polymerases to produce *in vitro* transcribed RNA.

In a general method for amplifying a polynucleotide, Loewy teaches the utilization of oligonucleotide sequences (adapters) comprising an RNA polymerase promoter site wherein said oligonucleotides (adapters) comprising the RNS polymerase promoter site are joined (ligated) to the target sequence by means of *in vitro* transcription using one or more RNA polymerases to produce *in vitro* transcribed RNA (abstract and col. 2 to col. 3, line 36). Loewy teaches that this *in vitro* transcription based assay is advantageous because the method requires less than three enzymes and can require as few as one enzyme, namely RNA polymerase (col. 4, lines 61-64). Loewy teaches that the method can be performed under isothermal conditions and can be combined with amplification methods, such as e.g., PCR (col. 5, lines 1-8). Loewy further teaches that the combination of transcription amplification and target-specific ligation, thereby provides for greater specificity (col. 1, lines 42-54). Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to modify the adapter in the gene expression identification method of Kohroki et al to encompass a RNA polymerase promoter site for the advantages or convenience of performing an *in vitro* transcription of RNA with few reagents under isothermal conditions. Likewise, one of ordinary skill in the art would have been motivated to combine the transcriptional based assay as taught by Loewy in the differential display gene expression assay of Kohroki et al for the advantages of greater specificity of identification of target sequences as taught by Loewy.

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8. Claims 3-4, 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohroki et al in view of Loewy as previously applied above and further in view of Weinstein et al (US 6,270,966 B1, August 7, 2001). Regarding claims 3-4, 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, and 31-32, Kohroki et al in view of Loewy teach a method for the identification and characterization of gene expression in one or more samples using differential display combined with an *in vitro* transcription as discussed above. The references do not expressly teach wherein the gene expression is compared and/or characterized using a database associated with known genes and wherein comparison are conducted by means of a software operated on a microprocessor. Weinstein et al teach a general method of differential display for identifying expressed genes. Weinstein et al teach wherein results obtained by differential display are compared to existing databases of known DNA sequences to identify expressed genes using computer-aid comparison programs (col. 12, lines 58-67 to col. 13, lines 1-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention have been made to compare results obtained by the gene expression identification method as taught by Kohroki et al in view of Loewy by a computer-based software using existing databases based on teaching known in the art as suggested by Weinstein et al.

Conclusion

9. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to

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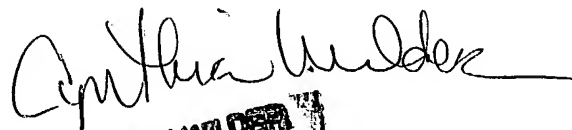
cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


CYNTHIA WILDER
PATENT EXAMINER
7/13/2004